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U.S. Environmental Protection Agency
Office of Pollution Prevention and Toxics
Confidential Business Information Center (CBIC) – TS7407M
EPA East Building, Room 6428
1201 Constitution Avenue, NW
Washington, DC 20004-3302

Dear Sir of Madam:

Reference: Consolidated PMN P-12 0450 and P-12-0451 [( ]

Consent Order

Please find enclosed the above-identified Consent Order executed on behalf of [ ] or the Company).

We very much appreciate the time and resources that the Environmental Protection Agency (EPA or the Agency) devoted to timely negotiating the Consent Order with [ ]. We do wish to emphasize that the negotiations focused on the binding requirements in the Consent Order section of the document and that the language in the non-binding Preamble section, particularly that which reflects EPA's assessments and conclusions, was not negotiated. To that end, it is reiterated that, as stated in Section VII of the Consent Order section, consenting to the entry of the Order and agreeing to be bound by its terms does not constitute an admission by the Company as to the facts or conclusions underlying the Agency's determinations in this matter.

Again, we thank the Agency for the time and effort it expended to finalize the Consent Order and we look forward to its successful implementation.

Very truly yours,

Via Federal Express
Enclosure:

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF POLLUTION PREVENTION AND TOXICS

REGULATION OF NEW CHEMICAL SUBSTANCES

PENDING DEVELOPMENT OF INFORMATION

In the matter of:	)	Premanufacture Notice Numbers:
	)	
	)	
	)	
	)	
	)	
[ ]	)	P-12-450 and 451
	)	
	)	
	)	
	)	
	)	

Consent Order and Determinations Supporting Consent Order

TABLE OF CONTENTS

I. INTRODUCTION

Under the authority of § 5(e) of the Toxic Substances Control Act ("TSCA") (15 U.S.C. 2604(e)), the Environmental Protection Agency ("EPA" or "the Agency") issues the attached Order, regarding premanufacture notices ("PMNs") P-12-450 and 451 for the chemical substances P-12-450–[ )-

] and P-12-451--[

] submitted by [

] ("the Company"), to take effect upon expiration of the PMN review period. The Company submitted the PMNs to EPA pursuant to § 5(a)(1) of TSCA and 40 CFR Part 720.

Under § 15 of TSCA, it is unlawful for any person to fail or refuse to comply with any provision of § 5 or any order issued under § 5. Violators may be subject to various penalties and to both criminal and civil liability pursuant to § 16, and to specific enforcement and seizure pursuant to § 17. In addition, chemical substances subject to an Order issued under § 5 of TSCA, such as this one, are subject to the § 12(b) export notice requirement.

II. SUMMARY OF TERMS OF THE ORDER

The Consent Order for these two PMN substances requires the Company to:

(a) submit to EPA certain tiered environmental fate and physical/chemical testing on a representative PMN substance, P-09-245. For Tier 1 testing, it must be submitted on the

schedule established for Consent Order P-09-245 and 246 and for Tiers 2 and 3 at least 14 weeks before manufacturing (including import) a total of [ ] kilograms (kgs) and [ ] kgs of the four PMN substances, P-09-245 and 246 and P-12-450 and 451;

(b) analyze and report to EPA [ ]* impurities;

(c) not exceed the maximum established levels of [ ] impurities; and

(d) maintain certain records.

Although a Consent Order for Contract Manufacturer is not attached to extend the requirements in this Order to an identified Contract Manufacturer, the Company may use a Contract Manufacturer in the future, if a modification of this Order to add a Consent Order for a Contract Manufacturer is approved and signed by EPA and signed by the Contract Manufacturer. This Consent Order establishes the requirements for the Company if a Contract Manufacturer manufactures the PMN substances. Prior to using a Contract Manufacturer, the Company must submit to EPA the Contract Manufacturer identity and other manufacturing process, and exposure, and release information concerning the Contract Manufacturer. The Contract Manufacturer would be required to keep records of quantities manufactured, but the Company must submit to EPA the required testing.

III. CONTENTS OF PMNS

By signing this Order, the Company represents that it has carefully reviewed this document and agrees that all information herein that is claimed as confidential by the Company

*As used in both the Preamble and Consent Order of this document, the terms [ ] mean [ ]

is correctly identified within brackets and that any information that is not bracketed is not claimed as confidential. To make this document available for public viewing, EPA will remove only information contained within the brackets.

Confidential Business Information Claims (Bracketed in the Preamble and Order): company identity, specific chemical identity, production volumes, manufacturing process, processing, and use information, and other information.

Chemical Identities:

Specific: **P-12-450--** [

] and **P-12-451--**[

]

Generic: Partially fluorinated alcohol, reaction products with phosporus oxide (P205) amine salts

Use: Specific: [

]

Generic use: Coating additive, surface active agent

Maximum 12-Month Production Volume: [ ] kgs

Test Data Submitted with PMN and During the Review Period and previously by this Company (many acronyms are subsequently explained more fully in section IV below where the results of the studies are discussed): Local Lymph Node Assay; Skin irritation, Eye irritation, Oral LD50 (rat); Bacterial Reverse Mutation, Chromosome Aberration in Mammalian Cells; Acute

Inhalation Toxicity; Biopersistence and pharmacokinetic Screen (rat); 7-day repeated dose oral gavage (rat); Daphnia Screen; 48-hr Daphnia EC 50; 21-day Daphnia Chronic study; 96-hr Algae Growth InhibitionTrout LC50; 2 Algal Screens; 96-hr Algae Growth Inhibition; Ready Biodegradability; Activated Sludge Respiration Inhibition; Flash Point; Adsorption/Desorption; Auto Ignition Temperature; Melting Point; Flash point (Flammability, Solids); Octanol/Water Partition Coefficient; Relative Density Surface Tension; Appearance of Substance; Boiling Point Vapor Pressure; and Water Solubility.

Toxicity Studies on [ ]:

[ ]-11560 [ ]-24748: [ ] Screening 10-Dose Oral Gavage Study in Rats;
[ ]-18510 [ ]: Repeated Dose Oral Toxicity Two-Week Gavage Study 3 volumes; Repeated dose, 90-day Study with Reproductive Screen

IV. EPA'S ASSESSMENT OF EXPOSURE AND RISK

The following are EPA's predictions regarding the probable toxicity, human exposure and environmental release of the PMN substances, based on the information currently available to the Agency.

Human Health Effects and Fate Summary: EPA has concerns for potential incineration or other decomposition products of the PMN substances. EPA also has concerns for the PMN substances that under some conditions of use-- particularly non-industrial, commercial, or consumer use-- could cause lung effects, based on limited data on some perfluorinated compounds. EPA required the Company to perform an Acute Inhalation study before manufacture to test whether these substances caused lung effects. An Acute Inhalation study in rats on a formulation of P-

11-91 was conducted over a 4-hour exposure period. The doses for the study were 1.2 and 2.0 mg/L. No deaths were seen at these concentrations. The approximate lethal concentration (ALC) was estimated to be greater than 2.0 mg/L (2000 mg/m3). The ALC is consistent with a low concern for acute inhalation toxicity.

EPA expects that the PMN substances will degrade based on [other perfluorinated acids]. The PMN substances may degrade to [ ] Based on information submitted to EPA during the PMN review period, the PMN substances have [ ]. EPA has agreed that for routine analysis, the Company may analyze the starting material, the [ ] for the following analytes: [ ]. The Company will also annually analyze the starting material, [ ] for perfluorooctanoic acid (PFOA), including establishing calibration curves where the LOQ is [ ]. However, at initial manufacture and at least annually thereafter, the Company has agreed to analyze representative samples of the "Initially Isolated Formulations"of the final formulation of the PMN substances. "Initially Isolated Formulations" is defined in the Definitions section of this Consent Order (Attachment A).

The Company will continue to work towards reducing the maximum amount of impurities [ ]. During commercial production, these impurities are produced partly by [ ]

The Company has agreed to seek ways to minimize these impurities. The Company, in consultation with EPA, has agreed to [

]. The Company is also evaluating other chemical management steps, which include [

]. To further document and control the actual contamination and efforts to reduce the impurity levels, the Company will limit the maximum impurity levels in the starting material, [ ] not to exceed the currently attainable levels (see Tables 1 and 2 in the Chemical Synthesis and Composition section of the attached Consent Order), and will report the various impurities [ ] annually.

EPA is concerned that these perfluorinated degradation products may be released to the environment from incomplete incineration of the PMN substances at low temperatures. EPA has preliminary evidence, including data on other [ ], that suggests that, under some conditions, the PMN substances could degrade in the environment. EPA has concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT) to people, wild mammals, and birds based on data on analog chemicals, including PFOA and [ ]. The presumed perfluorinated degradants for these PMN substances include [ ]. There is limited toxicological data in animals on [ ] or precursors, which is summarized below.

PFOA is expected to persist for years in the environment. Biodegradation and photolysis tests of analogous substances indicate little or no biodegradation or photolysis of perfluoroalkyl compounds. Bioaccumulation concerns are based on the measured presence of certain

perfluoroalkyl compounds, including PFOA, in wildlife and in human blood samples. Toxicity studies on PFOA indicate developmental, reproductive and systemic toxicity in various species. Cancer may also be of concern. These factors, taken together, raise concerns for potential adverse chronic effects in humans and wildlife. For additional information about PFOA, consult the EPA regulatory docket at OPPT-2003-0012. Additional information about PFOA,], and other perfluorinated substances may also be found in the *Administrative Record for PFOS, PFOA, and Telomers and Related Chemicals (AR-226). Administrative Record (AR-226)* is not currently available online, but copies can be requested on CD-ROM from the EPA Docket office by calling 202/566-0280 or sending an email request to oppt.ncic@epa.gov.

Limited toxicological, ecological, and fate data now exist on [ ] and some of the [ ]-derived polymers and other substances; see the PMN docket for data for these specific PMNs. A pharmacokinetics study on [ ] and for comparison perfluorobutane sulfonate (PFBS) in the cynomolgus monkey was submitted previously. This study indicates that the serum half-life of [ ] in these monkeys is less than 24 hours, whereas the half-life of PFOA in monkeys is 20.9 days in female monkeys, 32.6 days in male monkeys, and 3.8 years in humans. Another company also conducted a pharmacokinetics study on [ ] in rats that showed a serum half-life of one hour or less. These data and assessments support the assessment of reduced bioaccumulation of [ ] relative to PFOA.

The Company subject to this Consent Order has conducted a 90-day study with a reproductive screen on [ ]. Dose levels for this study were 0, 20, 100, and 500 mg/kg/day. EPA received this study at the end of July 2007. EPA review of this study concluded that a no-observed adverse effect level (NOAEL) was not established in this study for

systemic effects. There were numerous effects at 100 and 500 mg/kg/day on nasal tissue, liver, and thyroid, and at 500 mg/kg/day on body weight, the red blood cell system, clotting, and the kidney. The EPA reviewer concluded that although not clearly dose related, the elevation of two markers for liver toxicity across all treated groups of males in clinical chemistry, and the finding of focal necrosis in the liver across all treated groups of males, as well as, in treated recovery males, and the absence of this result in the controls, leads to the conclusion that no NOAEL was achieved.

For the one-generation reproductive toxicity study component of this study, the reproductive toxicity NOAEL is 500 mg/kg/day (the highest dose tested). The systemic toxicity NOAEL for P1 rats was 20 mg/kg/day based on decreased body weights/body weight gains at 100 and 500 mg/kg/day. The systemic toxicity NOAEL for F1 adults is 100 mg/kg/day based on reduced body weights/body weight gains and reduced food consumption at 500 mg/kg/day. The developmental toxicity NOAEL for F1 pups was 100 mg/kg/day based on decreased pup weights at 500 mg/kg/day. The rats (P1 generation; 20/sex/group) were administered gavage doses of 0, 20, 100 or 500 mg/kg/day for 70 days pre-mating, and then mated for a maximum of 2 weeks to produce 1 litter. Dosing was continued during mating, gestation, and lactation.

In addition, in 2005, another company conducted a Combined Repeated-Dose Toxicity Study with Reproduction/Developmental Screening Test, (OECD 422) in rats for [ ] and the [ ]. The EPA review of these subchronic and reproductive data on [ ] and the [ ] concluded that for [ ] no reproductive effects were seen at any dose. Dose levels were 50, 150, and 450/300 mg/kg/day (450 was reduced to 300 in the study on day 4 because of toxicity). However, systemic effects–primarily liver effects--were seen. EPA review

places the NOAEL for [ ] at 50 mg/kg/day. For the [ ], the doses were 25, 75, and 225 mg/kg/day. For systemic effects, no NOAEL was achieved with the Lowest-Observed Adverse Effect Level (LOAEL) at 25 mg/kg/day. For reproductive or developmental effects, the NOAEL is 75 mg/kg/day and the LOAEL is 225 mg/kg/day.

In 2006, another company submitted a 90-day Oral Repeated Dose Toxicity Study (OECD 408) for [ ]. Dose levels for this study were 0 (vehicle control), 10, 50, or 200 mg/kg/day and were based on the previous Combined Study (OECD 422). EPA review set the Lowest- Effect Level (LOEL) or LOAEL at 10 mg/kg/day, based on the body weight gain being lower in all treated groups of males. There was treatment-related toxicity in the liver and the red blood cell system (anemia) in males at 200 mg/kg/day. There was also increased peroxisomal beta oxidation activity at this dose level. Hepatotoxicity and peroxisomal beta oxidation activity have also been seen in studies on PFOA.

The significance of the finding of a benign brain tumor (astrocytoma) in one male rat in the high dose group is not clear. It is not the type of tumor normally associated with PFOA-type compounds, is not a rare tumor, and may be incidental. Abnormal histopathology was observed in the testes (2 males) and epididymides (1 male) at 200 mg/kg/day and is a sign of concern for male reproductive toxicity. Further testing should investigate male reproductive effects. From this study, the potential for immunotoxic effects is low. There have been some studies showing immunotoxic effects from PFOA. Any investigation of immunotoxic effects should await the corroborative testing now being conducted by EPA, Office of Research and Development. There were no clinical signs of neurotoxicity and there were no treatment-related effects in the functional observation battery or motor behavior.

Another 90-day study has been submitted to EPA on [ ]. EPA review of that study concluded that blood and liver effects were seen at the highest dose. This study had comparable doses with the other studies.

A one-generation reproduction/developmental toxicity study in mice on the [ ] was submitted to the Agency. In this study, pregnant mice were administered the test substance via gavage during gestation days 6-18. The NOAEL for maternal toxicity was 175 mg/kg/day (the highest dose tested). Signs of developmental toxicity were observed at 175 mg/kg/day on the postnatal day 1 and consisted of increases in the number of stillborn pups and pup deaths, reductions in the average pup body weight per litter with a pup with lenticular opacity. The NOAEL for developmental toxicty is 35 mg/kg/day.

A Chronic Toxicity, Carcinogenicity study was submitted in 2011. Doses were 2.5, 15, and 100 mg/kg/day for males and 5, 30, and 200 mg/kg/day for females. EPA review determined that no chronic toxicity or carcinogenicity effects were seen in the two lower doses. Due to limitations in the study no determination could be made for the highest doses.

These and other data indicate a different and less toxic profile for [ ] (a presumed environmental degradant of the PMN substances) than for PFOA. However, based on: (1) the persistence of [ ]; (2) potential intermediate fate products; and, (3) the possibility or likelihood that this substance may be used as a major substitute for some uses of PFOA, EPA believes that more information is needed on the toxicity of [ ] and possibly other environmental degradants, and the fate and physical/chemical properties of [ ]-derived or related polymers in the environment.

EPA also believes that additional reproductive and long-term toxicological testing on [ ] in animals is warranted. To this end, the Company has conducted a 90-day Repeated Dose Study With Reproductive Screen. EPA expects that a modified reproductive test (OECD 421, modified) will be conducted by another company. The modifications for the reproductive test include: (1) increase the parental sample size to 20; (2) the duration of the study should be extended to until the pups have reached sexual maturation; (3) parental males should be dosed for 10 weeks prior to mating; (4) dosing of the parental animals should be continued through lactation and then the pups should be directly dosed until they reach sexual maturation; (5) pup body weight should be recorded on lactation days 0, 4, 7, 14, and 21, and then at weekly intervals, (6) litter size can be standardized to 4 pups/litter on lactation day 4 (optional); (7) at weaning one pup/sex/litter can be randomly selected to follow until sexual maturation; and (8) the time of sexual matuation should be recorded (i.e. vaginal opening and preputial separation).

EPA may still seek additional avian reproduction testing (OECD 206) in mallard ducks and Life-Cycle testing in fish. In addition, comparative data, especially on the pharmacokinetics of [ ] and other perfluorinated substances will be developed by testing of the National Toxicology Program (NTP) in the so-called Perfluorinated Compounds Class Study.

Environmental Effects Summary: EPA expects the PMN substances or the degradants to be highly persistent. During the review period, the Company provided acute fish (rainbow trout), aquatic invertebrate (*Daphnia magna),* and algae (*Pseudokirchneriella subcapitata)* toxicity

studies on a formulation [ ] containing P-12-450. The tests were acceptable. Two additional algal "range-finding" tests were conducted on two different formulations of P-12-450].

For fish, the semi-static 96-hour test with nominal concentration of 0 (dilution water control), 7.5, 15, 30, 60, and 120 mg a.i./L total solids with one renewal after 48 hours. The 96-hour LC50 was >102 mg/L (mean-measured value).

Green algae at a nominal cell desity of 10,000 cell/ml, were exposed to the test substance at nominal concentrations of 0 (blind control), 1.48, 4.44, 13.3, 40.0, and 120 mg total solids/L. The 96-hour EC50 for biomass, growth rate, and yield was >105 mg/L. The NOEC was 34.3 mg/L, the LOEC 105 mg/L and the chronic value was 60.0 mg/L

From the submitted test data, the updated acute Concentration of Concern (COC) for both P-12-450 and 451 is 20,000 ppb. Based on fish and aquatic invertebrate acute to chronic ratios (ACR) of 10, the chronic values were 10 mg/L The assessment factor of 10 yields 1.0 mg/L or 1000 ppb. This indicates a low ecological toxicity hazard for P-12-450 and 451.

Also, [ ] conducted a 21-day Daphnid chronic toxicity test. This test resulted in no statistically significant adverse effects at the hightest test concentration. From the acceptable 21-day Daphnid chronic toxicity test data and the previous data the COCs remain at 20,000 ppb (acute) and 1,000 ppb (chronic) which indicates a low ecological hazard. There may be a high degree of uncertainty for fish since the chronic COC is based on acute data and chronic fish testing (fish early life stage testing) could be warranted. This testing is "pended" in the Consent Order.

Some ecotoxicity data on [; has been submitted to EPA including an Avian Reproduction Test in Bobwhite quail. EPA received the Avian Reproduction test on [ ] in 2011. The test was conducted according to OPPTS 850.2300, OECD 206, and FIFRA Subdivision E, Section 71-4 guidelines and under GLP conditions. Results showed no adverse effects in adult northern bobwhite quail exposed to 1,000 ppm, 5,000 ppm or 10,000 ppm for body weight, feed consumption, or reproductive parameters. In addition, no effects were observed in the offspring of the exposed adults. The NOEC is 10,000 ppm or 964 mg/kg/day. Although the original test recommendations included analysis for of the livers of the adult birds as well as the blood and livers of the offspring for the presence of , the fact that the analysis was not performed did not alter the validation of the study considering the lack of effects seen in adult tissue at necropsy and the lack of signs of toxicity in both the adult and offspring as a whole. In summary, the NOEC remains 10,000 ppm or 964 mg/kg/day.

However, there is high concern for possible environmental effects from the potential persistent degradation product [ ]. As stated previously, the analog PFOA is persistent in the environment and has a long bioretention time in various species. It has been detected in a number of species of wildlife, including marine mammals. It is toxic to mammalian and other species. The presence in the environment and toxicological properties of PFOA continue to be investigated. Some limited ecotoxicological effects data exist on [ ] in fish, daphnia, algae, and birds. EPA believes development of additional chronic data on [ ] is warranted. These studies are being conducted by other companies.

Exposure and Environmental Release Summary: Thermal and simulated incineration testing

exists on some related p(lymers. This testing indicates that incomplete incineration products are formed at lower incir eration temperatures. Modified Zahn-Wellens and Semi-Continuous Activated Sludge (SCAS) biodegradation tests have been conducted on some related polymers. EPA has determined tha some related polymers degrade, while another did not show signs of degradation during the ti ne frame of the test. EPA has received and reviewed test data showing that certain pol mers with perfluoroalkyl substituents degrade to form perfluoroalkyl containing intermediate and perfluoroalkyl containing organic acids. EPA expects that these PMN substances will de grade.

The PMN subst nces will be manufactured at one submitter site in [

| days per year. The PMN substances will be manufactured into an [

]. The PMN substances may be released to water or via incineration to th air. There could be dermal exposure to 3 workers. Inhalation is expected to be negligibl based on low vapor pressure.

The PMN subst nces will be processed into formulations of [

] at [ ] or formulations of [waxes/floor finishes and stripper/cleaner formul ions] at [ ] The PMN substances may be released to wate , landfilled, or to the air via incineration. Dermal exposure to workers is possible.

The PMN subs nces will be used in [

] for [ ]

Occupational exposure are dermal and inhalation. There may be exposure to consumers and the coatings containing he PMN substances may be spray applied although exposures are

expected to be primarily dermal. The coatings contain |. The PMN substances may be released to water, landfilled, or via incineration to the air during use.

EPA does not expect a significant risk from spray use of the tested formulation. Based on the NOAEL of 24 mg/m3 in the second acute inhalation study and the projected consumer inhalation exposure, there is not a risk to consumers with an adequate margin of exposure of greater than 100, This would be considered an episodic exposure so an acute inhalation study addresses potential consumer risk.

V. EPA'S CONCLUSIONS OF LAW

The following findings constitute the basis of the Consent Order:

(a) EPA is unable to determine the potential for human health and environmental effects from exposure to the PMN substances and potential degradation products. EPA therefore concludes, pursuant to § 5(e)(1)(A)(i) of TSCA, that the information available to the Agency is insufficient to permit a reasoned evaluation of the human health and environmental effects of the PMN substances and potential degradation products.

(b) In light of the potential risk of human health and environmental effects posed by the uncontrolled manufacture, processing, distribution in commerce, use, and disposal of the PMN substances, EPA has concluded, pursuant to § 5(e)(1)(A)(ii)(I) of TSCA, that uncontrolled manufacture (which includes import), processing, distribution in commerce, use, and disposal of the PMN substances may present an unreasonable risk of injury to human health and the environment.

(c) In light of the estimated production volume of, and human exposure to the PMN substances and potential degradation products, EPA has further concluded, pursuant to § 5(e)(1)(A)(ii)(II) of TSCA, that the PMN substances will be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities, and there may be significant (or substantial) human exposure to the substance and potential degradation products.

VI. INFORMATION REQUIRED TO EVALUATE HUMAN HEALTH AND ENVIRONMENTAL EFFECTS

Triggered Testing. The Order prohibits the Company from exceeding specified production volumes unless the Company submits the information described in the Testing section of this Order in accordance with the conditions and test substance specified in the Testing section. The physical properties of the PMN substances and target analytes present technical challenges in conducting the required testing. EPA will review submitted protocols in a timely fashion as stated in the Consent Order and provide additional relevant information and input to the extent that it is known and not claimed confidential by other companies.

Pending Testing. The Order does not require submission of the following information at any specified time or production volume. However, the Order's restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMN substances will remain in effect until the Order is modified or revoked by EPA based on submission of the following or other relevant information.

EPA expects that protocols would be submitted prior to any additional toxicological testing required under this Consent Order. Due to the limited water solubility of some of these substances and consequent analytical difficulties, some modification of the protocols may be necessary. These and other modifications will be agreed upon between EPA and the Company.

(1) Because some concerns for the PMN substances are based on analogy between [ ] and PFOA, and because [ ] is a potential ultimate degradation product of the PMN substances, the following additional information on [ ] would be necessary to evaluate the human health and environmental effects which may be caused by the PMN substances: an avian reproduction test (OECD Guideline 206) in mallard ducks.

(2) Information on inhalation toxicology if the substance were to be sprayed by [commercial applicators that would generate significant respirable particles or respirable aerosol droplets and the exposure is chronic in nature] or sold for spray application use by consumers where use might be typically repeated in a chronic manner. This could include a repeated dose inhalation study with a bronchoalveolar lavage component and special attention to histopathology (inflammation and cell proliferation) or other relevant information. Based on current expected use, no additional mammalian toxicology testing is recommended for this exposure via inhalation.

(3) A chronic fish study (OPPTS 850.1300) on P-12-450 to better characterize chronic exposures and toxicity to fish.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

CONSENT ORDER

I. SCOPE OF APPLICABILITY AND EXEMPTIONS

(a) Scope. The requirements of this Order apply to all commercial manufacturing, processing, distribution in commerce, use and disposal of the following two chemical substances [

] (P-12-450) and [

] (P-12-451) (the "PMN substances") in the United States by [ ] ("the Company"), except to the extent that those activities are exempted by paragraph (b).

(b) Exemptions. Manufacturing of the PMN substances is exempt from the requirements of this Order (except the requirements in the Recordkeeping and Successor Liability Upon Transfer Of Consent Order sections) only to the extent that (1) these activities are conducted in full compliance with all applicable requirements of the following exemptions, and (2) such compliance is documented by appropriate record keeping as required in the Recordkeeping section of this Order.

(1) Export. Until the Company begins commercial manufacture of the PMN substances

for use in the United States, the requirements of this Order do not apply to manufacture, processing or distribution in commerce of the PMN substances solely for export in accordance with TSCA §12(a) and (b), 40 CFR 720.3(s) and 40 CFR Part 707. However, once the Company begins to manufacture the PMN substances for use in the United States, no further activity by the Company involving the PMN substances is exempt as "solely for export" even if some amount of the PMN substances is later exported. At that point, the requirements of this Order apply to all activities associated with the PMN substances while in the territory of the United States. Prior to leaving U.S. territory, even those quantities or batches of the PMN substances that are destined for export are subject to terms of the Order, and count towards any production volume test triggers in the Testing section of this Order.

(2) Research & Development ("R&D"). The requirements of this Order do not apply to manufacturing, processing, distribution in commerce, use and disposal of the PMN substances in small quantities solely for research and development in accordance with TSCA §5(h)(3), 40 CFR 720.3(cc), and 40 CFR 720.36. The requirements of this Order also do not apply to manufacturing, processing, distribution in commerce, use and disposal of the PMN substances when they are manufactured solely for non-commercial research and development per 40 CFR 720.30(i) and TSCA §5(i).

(3) Byproducts. The requirements of this Order do not apply to the PMN substances when they are produced, without separate commercial intent, only as a "byproduct" as defined at 40 CFR 720.3(d) and in compliance with 40 CFR 720.30(g).

(4) No Separate Commercial Purpose. The requirements of this Order do not apply to the PMN substances when they are manufactured, pursuant to any of the exemptions in 40 CFR 720.30(h), with no commercial purpose separate from the substance, mixture, or article of which

they are a part.

(5) Imported Articles. The requirements of this Order do not apply to the PMN substances when they are imported as part of an "article" as defined at 40 CFR 720.3(c) and in compliance with 40 CFR 720.22(b)(1).

(c) Automatic Sunset. If the Company has obtained for the PMN substances a Test Market Exemption ("TME") under TSCA §5(h)(1) and 40 CFR 720.38 or a Low Volume Exemption ("LVE") or Low Release and Exposure Exemption ("LoREX") under TSCA §5(h)(4) and 40 CFR 723.50(c)(1) and (2) respectively, any such exemption is automatically rendered null and void as of the effective date of this Consent Order.

II. TERMS OF MANUFACTURE, PROCESSING, DISTRIBUTION IN COMMERCE, USE, AND DISPOSAL PENDING SUBMISSION AND EVALUATION OF INFORMATION

PROHIBITION

The Company is prohibited from manufacturing the PMN substances in the United States, for any nonexempt commercial purpose, pending the development of information necessary for a reasoned evaluation of the human health and environmental effects of the substances, and the completion of EPA's review of, and regulatory action based on, that information, in accordance with the conditions described in this Order.

CHEMICAL SYNTHESIS AND COMPOSITION

(a) Restriction. The Company shall not manufacture the PMN substances, P-12-450 and 451 unless the [| starting material is in compliance with and does not exceed the limits

specified in Table 1 and Table 2. The Company shall analyze the Initially Isolated Formulations of the PMN substances for the analytes specified in Table 3 upon initial commencement of manufacture, and at least annually analyze and report thereafter, until one year after the date of the last joint manufacture or processing of a product that contains products at the facility. The Company shall report to the Agency the levels of impurities

| associated with the PMN substances, P-12-450 and 451 manufactured by the Company, as specified below. For routine analysis, the Company shall analyze the starting material, [| for the following analytes shown in Table 1 below:

]. The Company will also annually analyze the starting material, [--'], for the analyte [ ] shown in Table 2, below. The Company shall make its best effort to minimize these impurities and to seek to eliminate them.

(b) Analysis and Reporting. The Company shall analyze representative samples of the Initially Isolated Formulations of the PMN substances, P-12-450 and 451 manufactured (which includes import) by the Company to determine compliance with the requirements in paragraph (a). The Company shall also analyze the Initially Isolated Formulations of the PMN substances at each manufacturing facility both (1) at the initial commencement of non-exempt manufacture of the PMN substances at that facility, and (2) at least annually thereafter during every year in which the PMN substances are manufactured at that facility. If any new facility of manufacture is added or if the process of manufacture of the PMN substances is significantly altered, then the Initially Isolated Formulation of the PMN substances must be analyzed at commencement, and annually

annually thereafter as set forth above. If the PMN substances are imported, the Company shall obtain from the foreign manufacturer written documentation to certify that representative samples of the imported form of the PMN substances have been analyzed, consistent with the requirements of this paragraph (b), and determined to comply with the requirements of paragraph (a). The Company shall report the above analysis to EPA at initial commencement of manufacture (which includes import) and again if any new manufacturing facility is added or if the process of manufacture of the PMN substances or any intermediate thereof is significantly altered. The Company shall continue to report these impurity levels to EPA annually, in a cycle complementary to the [ ]. In addition to the reporting for the Initially Isolated Formulations of the PMN substances themselves, the Company shall, for the [ ] starting material, annually report (1) the average values and the range of values, including outlying data, for the routine analysis for the analytes specified in Table 1 and (2) the results of the annual analysis for the analyte specified in Table 2.

TABLE 1:

TO BE ROUTINELY AN LYZED IN [ ] STARTING MATERIAL

Analyte	CAS Number	Limit in [ ]
[ ]	[ ]	] minimum
[ ] [ ]	]]	[(combined)*
[ ]	[ ]	[
[ ] [ ]	[ ] [ ]	[ ] (combined)
[ ]	[ ]	[ ]
[ ] [ ]	]]	[ ] (combined)

*

TABLE 2:

TO BE ANALYZED A LEAST ANNUALLY IN [ ] STARTING MATERIAL

Analyte	CAS Number	Limit in [ ]
[ ]	[ ]	[ ]

TABLE 3:

TO BE ANALYZED AT START-UP AND AT LEAST ANNUALLY THEREAFTER IN THE INI IALLY ISOLATED FORMULATIONS OF THE PMN SUBS TANCES

Analyte	CAS Number	Estimated Maximum in Initially Isolated Formulations of the PMN substances
[ ] [ ]	]]	[ ](combined)
[ ] [ ]	]]	[ ] (combined)
[ ]	[ ]	[ ]

MANUFACTURING

(a)(1) Prohibition. The Company shall not cause, encourage, or suggest the manufacture (including import) of the PMN substances by any other person. However, the Company may communicate to any other person the existence of the 5(e) Consent Order and TSCA Inventory status for the PMN substances.

(2) Sunset Following SNUR. Subparagraph (a)(1) shall expire 75 days after promulgation of a final significant new use rule ("SNUR") governing the PMN substances under section 5(a)(2) of TSCA unless the Company is notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Company is so notified, subparagraph (a)(1) shall not expire until EPA notifies the Company in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.

(3) Notice of SNUR. When EPA promulgates a final SNUR for the PMN substances and subparagraph (a)(1) expires in accordance with subparagraph (a)(2), the Company shall notify each person whom it causes, encourages or suggests to manufacture or import the PMN substances of the existence of the SNUR.

(b) Contract Manufacturer. Notwithstanding paragraph (a), the Company may cause a "Contract Manufacturer" outside the Company to manufacture or import the PMN substances according to the following conditions:

(1) The Contract Manufacturer must be under contract to the Company to manufacture or import the PMN substances solely for the Company. The contract must specify the identity of the PMN substances, the total quantities to be manufactured, and the basic technology to be used for manufacturing.

(2) The Company shall obtain from each Contract Manufacturer a signed copy of the

Consent Order for Contract Manufacturer (to be attached to this Order as Attachment C) and submit the copy to EPA along with the name, address, and telephone number of a responsible official of the Contract Manufacturer. The Contract Manufacturer or Company must receive a fully executed copy of the Consent Order for Contract Manufacturer from EPA before the Contract Manufacturer may begin manufacture or import.

(3) If at any time, the Company learns that the Contract Manufacturer has failed to comply with any of the conditions specified in the Consent Order for Contract Manufacturer, the Company shall immediately cease to cause the Contract Manufacturer to manufacture or import the PMN substances, unless the Contract Manufacturer is in compliance with a SNUR for the PMN substances, or unless the Company is able to document each of the following:

(i) That the Company has, within 5 working days, notified the Contract Manufacturer in writing that the Contract Manufacturer has failed to comply with any of the conditions specified in the Consent Order for Contract manufacturer.

(ii) That, within 15 working days of notifying the Contract Manufacturer of the noncompliance, the Company received from the Contract Manufacturer, in writing, a statement of assurance that the Contract Manufacturer is aware of the terms of the Consent Order for Contract Manufacturer and will comply with those terms.

(iii) If, after receiving a statement of assurance from the Contract Manufacturer under subparagraph (b)(ii) of this Section, the Company has notice or knowledge that the Contract Manufacturer has failed to comply with any of the conditions specified in the Consent Order for Contract Manufacturer, the Company shall immediately cease to cause the Contract Manufacturer to manufacture or import the PMN substances, shall notify EPA of the failure to comply, and shall resume causing the Contract Manufacturer to manufacture or import the PMN

substances only upon written notification from the Agency.

DISTRIBUTION

(a) Export Notice Requirement. No later than the date of distribution, the Company shall notify in writing any person to whom it distributes the PMN substances for "commercial use" or "industrial use" that, due to the issuance of this Consent Order under section 5(e) of TSCA, the PMN substances are subject to the export notification requirements of TSCA section 12(b) and 40 CFR Part 707 Subpart D. Such notice shall contain, in the form in which it appears in this Consent Order, the following information: (1) the PMN number, and (2) either (A) the specific chemical identity of the PMN substance, or (B) if the specific chemical identity is confidential, the generic chemical identity.

TESTING

(a) Section 8(e) Reporting. Reports of information on the PMN substances which reasonably supports the conclusion that the PMN substances present a substantial risk of injury to health or the environment, which is required to be reported under TSCA section 8(e) shall reference the appropriate PMN identification number for these substances and contain a statement that the substances are subject to this Consent Order. Additional information regarding section 8(e) reporting requirements can be found at www.epa.gov/oppt/tsca8e.

(b) Notice of Study Scheduling. The Company shall notify, in writing, the EPA Monitoring Assistance and Media Programs Division (2227A), Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, D.C. 20460, of the following information within 10 days of scheduling any study

required to be performed pursuant to this Order, or within 15 days after the effective date of this Order, whichever is later:

(1) The date when the study is scheduled to commence;

(2) The name and address of the laboratory which will conduct the study;

(3) The name and telephone number of a person at the Company or the laboratory whom EPA may contact regarding the study; and,

(4) The appropriate PMN identification number for each substance and a statement that the substance is subject to this Consent Order.

The written notice should be submitted to EPA as follows:

Postal Mail Address

U.S. Environmental Protection Agency

GLP Section Chief – Pesticides, Water and Toxics Branch

Monitoring Assistance and Media Programs Division (2227A)

Office of Enforcement and Compliance Assurance

1200 Pennsylvania Avenue, N.W.

Washington, DC 20460

Courier Delivery Address

U.S. Environmental Protection Agency

GLP Section Chief – Pesticides, Water and Toxics Branch

Monitoring Assistance and Media Programs Division (2227A)

Office of Enforcement and Compliance Assurance

Room 7117B

1200 Pennsylvania Avenue, N.W.

Washington, DC 20004

(c) Good Laboratory Practice Standards and Test Protocols. Each study required to be performed pursuant to this Order must be conducted according to TSCA Good Laboratory Practice Standards at 40 CFR Part 792 and using methodologies generally accepted in the relevant scientific community at the time the study is initiated. Before starting to conduct any study, the Company must obtain approval of test protocols from EPA by submitting written protocols. EPA will respond to the Company within 4 weeks of receiving the written protocols. Published test guidelines specified in paragraph (d) provide general guidance for development of test protocols, but are not themselves acceptable protocols. Approval of the test protocol does not mean pre-acceptance of test results.

(d) Triggered Testing Requirements. (i) The Company must conduct the following studies on the related substance [

] (P-09-245), on the schedule established for the Consent Order for Premanufacture Notice Numbers P-09-245 and P-09-246 as representative testing for the PMN substances, P-12-450 and P-12-451. The Company must submit final reports and underlying data in accordance with the conditions specified in the Testing section of the Consent Order for P-09-245 and P-09-246 and as modified.

Production Limit	Study	Guideline
As the schedule for the Consent Order for P-09-245 and 246	Modified Semi-Continuous Activated Sludge (SCAS) with Analysis for degradation products	OPPTS 835.5045; OECD 302A
	UV visible light absorption	OPPTS 830.7050, OECD 101
	Direct Photolysis, if wavelengths greater than 290 nm are absorbed in the previous test (OPPTS 830.7050)	OPPTS 835.2210
	Indirect Photolysis Screening Test	OPPTS 835.5270
	Hydrolysis as a function of pH and temperature	OPPTS 835.2130, OECD 111
	Anaerobic Biodegradability of Organic Compounds in Digested Sludge	OECD 311

(ii) The Company is prohibited from manufacturing or importing the PMN substances P-12-450 and P-12-451 beyond the aggregated manufacture and import volumes of [| kilograms and [ ] kilograms of the two PMN substances, and the two chemical substances [

] (P09-245) and [

] (P-09-246) combined ("the production limits"), unless the Company conducts the following studies on the substance described in PMN P-09-245 and submits final reports and underlying data in accordance with the conditions specified in the Testing section of the Consent Order for Premanufacture Notice Numbers P-09-245 and P-09-246 and as modified.

[	] kgs	Phototransformation of Chemicals On Soil Surfaces–2 soils	Draft OECD guideline Jan. 2002
		Aerobic Sewage Treatment Plant (STP) (Activated Sludge Units)	OECD 303A
		Aerobic and Anaerobic Transformation in Aquatic Sediment Systems	OECD 308
		Aerobic Transformation in Soil	OECD 307
[	] kgs	Anaerobic Transformation in Soil	OECD 307

(ii) The test substance shall be the PMN substance described in P-09-245. Chemical composition of the test substance shall be verified and a certificate of analysis submitted to EPA.

(iii) Chemical composition of the test substance must be fully characterized. For polymers, characterization includes all information required on pages 5 and 6 of the PMN form (i.e. EPA Form 7710-25), except that data on residuals are only required for fluorinated substances. Although EPA understands that complete mass balance may not be achievable for the specified analytes, the Company shall attempt mass balance to the greatest extent practicable. EPA prefers that the Company test the commercial substance.

(iv) The Company must test for the following analytes in the Biodegradation Tests (OECD 307, OECD 308, OECD 311, OPPTS 835.5045 or OECD 302A, and OECD 303A) : [

].

(v) Because the environmental fate pathway for photolysis may be different than for biodegradation, the Company must test for the following analytes in the Abiotic Tests: identify the major fluorinated fragments and volatiles including: [

(e) Test Reports. The Company shall: (1) conduct each study in good faith, with due care, and in a scientifically valid manner; (2) promptly furnish to EPA the results of any interim phase of each study; and (3) submit,with an additional sanitized copy, if confidential business information is involved), the final report of each study and all underlying data ("the report and data") to EPA no later than 14 weeks prior to exceeding the applicable production limit. The final report shall contain the contents specified in 40 CFR 792.185. Underlying data shall be submitted to EPA in accordance with the applicable "Reporting," "Data and Reporting," and "Test Report" subparagraphs in the applicable test guidelines. However, for purposes of this Consent Order, the word "should" in those subparagraphs shall be interpreted to mean "shall" to make clear that the submission of such information is mandatory. EPA will require the submission of raw data such as slides and laboratory notebooks only if EPA finds, on the basis of professional judgment, that an adequate evaluation of the study cannot take place in the absence of these items.

(f) Testing Waivers. The Company is not required to conduct a study specified in paragraph (d) of this Testing section if notified in writing by EPA that it is unnecessary to conduct that study.

(g) Equivocal Data. If EPA finds that the data generated by a study are scientifically equivocal, the Company may continue to manufacture the PMN substances beyond the applicable production limit. To seek relief from any other restrictions of this Order, the Company may

make a second attempt to obtain unequivocal data by reconducting the study under the conditions specified in paragraphs (b), (c), and (e)(1) and (e)(2). The testing requirements may be modified, as necessary to permit a reasoned evaluation of the risks presented by the PMN substances, only by mutual consent of EPA and the Company.

(h) EPA Determination of Invalid Data.

(1) Except as described in subparagraph (h)(2), if, within 6 weeks of EPA's receipt of a test report and data, the Company receives written notice that EPA finds that the data generated by a study are scientifically invalid, the Company is prohibited from further manufacture of the PMN substances beyond the applicable production limit.

(2) The Company may continue to manufacture the PMN substances beyond the applicable production limit only if so notified, in writing, by EPA in response to the Company's compliance with either of the following subparagraphs (h)(2)(i) or (h)(2)(ii).

(i) The Company may reconduct the study in compliance with paragraphs (b), (c), and (e)(1) and (e)(2). If there is sufficient time to reconduct the study and submit the report and data to EPA at least 14 weeks before exceeding the production limit as required by subparagraph (e)(3), the Company shall comply with subparagraph (e)(3). If there is insufficient time for the Company to comply with subparagraph (e)(3), the Company may exceed the production limit and shall submit the report and data in triplicate to EPA within a reasonable period of time, all as specified by EPA in the notice described in subparagraph (h)(1). EPA will respond to the Company, in writing, within 6 weeks of receiving the Company's report and data.

(ii) The Company may, within 4 weeks of receiving from EPA the notice described in subparagraph (h)(1), submit to EPA a written report refuting EPA's finding. EPA

will respond to the Company, in writing, within 4 weeks of receiving the Company's report.

(i) Company Determination of Invalid Data.

(1) Except as described in subparagraph (i)(2), if the Company becomes aware that circumstances clearly beyond the control of the Company or laboratory will prevent, or have prevented, development of scientifically valid data under the conditions specified in paragraphs (c) and (e), the Company remains prohibited from further manufacture of the PMN substances beyond the applicable production limit.

(2) The Company may submit to EPA, within 2 weeks of first becoming aware of such circumstances, a written statement explaining why circumstances clearly beyond the control of the Company or laboratory will cause or have caused development of scientifically invalid data. EPA will notify the Company of its response, in writing, within 4 weeks of receiving the Company's report. EPA's written response may either:

(i) allow the Company to continue to manufacture the PMN substances beyond the applicable production limit, or

(ii) require the Company to continue to conduct, or to reconduct, the study in compliance with paragraphs (b), (c), and (e)(1) and (e)(2). If there is sufficient time to conduct or reconduct the study and submit the report and data to EPA at least 14 weeks before exceeding the production limit as required by subparagraph (e)(3), the Company shall comply with subparagraph (e)(3). If there is insufficient time for the Company to comply with subparagraph (e)(3), the Company may exceed the production limit and shall submit the report and data in triplicate to EPA within a reasonable period of time, all as specified by EPA in the notice described in subparagraph (i)(2). EPA will respond to the Company, in writing, within 6 weeks

of receiving the Company's report and data, as to whether the Company may continue to manufacture beyond the applicable production limit.

(j) Unreasonable Risk.

(1) EPA may notify the Company in writing that EPA finds that the data generated by a study are scientifically valid and unequivocal and indicate that, despite the terms of this Order, the PMN substances will or may present an unreasonable risk of injury to human health or the environment. EPA's notice may specify that the Company undertake certain actions concerning further testing, manufacture, processing, distribution, use and/or disposal of the PMN substances to mitigate exposures to or to better characterize the risks presented by the PMN substances. Within 2 weeks from receipt of such a notice, the Company must cease all manufacture, processing, distribution, use and disposal of the PMN substances, unless either:

(2) within 2 weeks from receipt of the notice described in subparagraph (j)(1), the Company complies with such requirements as EPA's notice specifies; or

(3) within 4 weeks from receipt of the notice described in subparagraph (j)(1), the Company submits to EPA a written report refuting EPA's finding and/or the appropriateness of any additional requirements imposed by EPA. The Company may continue to manufacture, process, distribute, use and dispose of the PMN substances in accordance with the terms of this Order pending EPA's response to the Company's written report. EPA will respond to the Company, in writing, within 4 weeks of receiving the Company's report. Within 2 weeks of receipt of EPA's written response, the Company shall comply with any requirements imposed by EPA's response or cease all manufacture, processing, distribution, use and disposal of the PMN substances.

(k) Other Requirements. Regardless of the satisfaction of any other conditions in this Testing section, the Company must continue to obey all the terms of this Consent Order until otherwise notified in writing by EPA. The Company may, based upon submitted test data or other relevant information, petition EPA to modify or revoke provisions of this Consent Order pursuant to Part VI. of this Consent Order.

RISK NOTIFICATION

(a) If as a result of the test data required under the terms of this Order, the Company becomes aware that any of the PMN substances may present a risk of injury to human health or the environment (or is so notified by EPA), the Company must incorporate this new information, and any information on methods for protecting against such risk, into a Material Safety Data Sheet ("MSDS") for those PMN substances, as described in 40 CFR section 721.72(c), within 90 days from the time the Company becomes aware of the new information. If the PMN substances are not being manufactured, processed, or used in the Company's workplace, the Company must add the new information to an MSDS before the PMN substances are reintroduced into the workplace.

(b) The Company must ensure that persons who will receive the PMN substances from the Company for either commercial or industrial use, or who have received the PMN substances from the Company for either commercial or industrial use, within 5 years from the date the Company becomes aware of the new information described in paragraph (a) of this section, are provided an MSDS containing the information required under paragraph (a) within 90 days from the time the Company becomes aware of the new information.

III. RECORDKEEPING

(a) Records. The Company shall maintain the following records until 5 years after the date they are created and shall make them available for inspection and copying by EPA in accordance with section 11 of TSCA:

(1) Exemptions. Records documenting that the PMN substances did in fact qualify for any one or more of the exemptions described in Section I, Paragraph (b) of this Order. Such records must satisfy all the statutory and regulatory recordkeeping requirements applicable to the exemption being claimed by the Company. Any amounts or batches of the PMN substances eligible for the Export exemption in Section I, Paragraph (b)(1) of this Order, are exempt from all the requirements in this Recordkeeping section, if the Company maintains, for 5 years from the date of their creation, copies of the export label and export notice to EPA, required by TSCA sections 12(a)(1)(B) and 12(b), respectively. Any amounts or batches of the PMN substances eligible for the Research and Development exemption in Section I, Paragraph (b)(2) of this Order, are exempt from all the requirements in this Recordkeeping section, if the Company maintains, for 5 years from the date of their creation, the records required by 40 CFR 720.78(b). For any amounts or batches of the PMN substances claimed to be eligible for any other exemption described in Section I, Paragraph (b) of this Order, the Company shall keep records demonstrating qualification for that exemption as well as the records specified in paragraphs (2) and (3) below, but is exempt from the other record keeping requirements in this Record keeping section;

(2) Records documenting compliance with the Chemical Synthesis and Composition section of this Order, including the results from routine analysis of representative samples of the

starting material, [ ], and at start-up and annually thereafter of the Initially Isolated Formulations of the PMN substances.

(3) Records documenting compliance with the Manufacturing, Distribution, and Testing sections of this Order.

(4) Records documenting the manufacture (including importation) volume of the PMN substances and the corresponding dates of manufacture and import.

(5) Records documenting the names and addresses (including shipment destination address, if different) of all persons outside the site of manufacture to whom the Company directly sells of transfers the PMN substances, the date of each sale or transfer, and the quantity of the substance sold or transferred on such date, wherein transfer does not include the distribution of small sample quantities (less than [ ] kilograms annually) of the PMN substances without charge.

(6) Records documenting the address of all sites of manufacture, processing, and use;

(7) Copies of material safety data sheets required by the Risk Notification section of this Order;

(8) Copies of any Transfer Documents and notices required by the Successor Liability section of this Order, if applicable; and

(9) The Company shall keep a copy of this Order (electronic or hard copy) at each of its sites where the PMN substances are manufactured, processed, or used.

(b) Applicability. The provisions of this Record keeping Section are applicable only to activities of the Company and its Contract Manufacturer, if applicable, and not to activities of the Company's customers.

(c) OMB Control Number. Under the Paperwork Reduction Act and its regulations at 5 CFR Part 1320, particularly 5 CFR 1320.5(b), the Company is not required to respond to this "collection of information" unless this Order displays a currently valid control number from the Office of Management and Budget (OMB), and EPA so informs the Company. The "collection of information" required in this TSCA §5(e) Consent Orders has been approved under currently valid **OMB Control Number 2070-0012.**

IV. REQUESTS FOR PRE-INSPECTION INFORMATION

(a) EPA's Request for Information. Pursuant to section 11 of TSCA and 40 CFR 720.122, EPA may occasionally conduct on-site compliance inspections of Company facilities and conveyances associated with the PMN substances. To facilitate such inspections, EPA personnel may contact the Company in advance to request information pertinent to the scheduling and conduct of such inspections. Such requests may be written or oral. The types of information that EPA may request may include, but are not limited to, the following:

(i) Expected dates and times when the PMN substances will be in production within the subsequent 12 months;

(ii) Current workshift schedules for workers who are involved in activities associated with the PMN substances and may reasonably be exposed to the PMN substances;

(iii) Current job titles or categories for workers who are involved in activities associated with the PMN substances and may reasonably be exposed to the PMN substances;

(iv) Existing exposure monitoring data for workers who are involved in activities associated with the PMN substances and may reasonably be exposed to the PMN substances;

(v) Records required by the Record keeping section of this Order; and/or

(vi) Any other information reasonably related to determining compliance with this Order or conducting an inspection for that purpose.

(b) Company's Response. The Company shall respond to such requests within a reasonable period of time, but in no event later than 30 days after receiving EPA's request. When requested in writing by EPA, the Company's response shall be in writing. To the extent the information is known to or reasonably ascertainable to the Company at the time of the request, the Company's response shall demonstrate a good faith effort to provide reasonably accurate and detailed answers to all of EPA's requests.

(c) Confidential Business Information. Any Confidential Business Information (CBI) that the Company submits to EPA pursuant to paragraph (b) shall be protected in accordance with §14 of TSCA and 40 CFR Part 2.

V. SUCCESSOR LIABILITY UPON TRANSFER OF CONSENT ORDER

(a) Scope. This section sets forth the procedures by which the Company's rights and obligations under this Order may be transferred when the Company transfers its interests in the PMN substances, including the right to manufacture the PMN substances, to another person outside the Company (the "Successor in Interest").

(b) Relation of Transfer Date to Notice of Commencement ("NOC").

(1) Before NOC. If the transfer from the Company to the Successor in Interest is

effective before EPA receives a notice of commencement of manufacture ("NOC") for the PMN substances from the Company pursuant to 40 CFR 720.102, the Successor in Interest must submit new PMNs to EPA and comply fully with Section 5(a)(1) of TSCA and 40 CFR part 720 before commencing manufacture of the PMN substances.

(2) After NOC. If the transfer from the Company to the Successor in Interest is effective after EPA receives a NOC, the Successor in Interest shall comply with the terms of this Order and shall not be required to submit new PMNs to EPA.

(c) Definitions. The following definitions apply to this Successor Liability section of the Order:

(1) "Successor in Interest" means a person outside the Company who has acquired the Company's full interest in the rights to manufacture the PMN substances, including all ownership rights and legal liabilities, through a transfer document signed by the Company, as transferor, and the Successor in Interest, as transferee. The term excludes persons who acquire less than the full interest of the Company in the PMN substances, such as a licensee who has acquired a limited license to the patent or manufacturing rights associated with the PMN substances. A Successor in Interest must be incorporated, licensed, or doing business in the United States in accordance with 40 CFR 720.22(3).

(2) "Transfer Document" means the legal instrument(s) used to convey the interests in the PMN substances, including the right to manufacture the PMN substances, from the Company to the Successor in Interest.

(d) Notices.

(1) Notice to Successor in Interest. On or before the effective date of the transfer, the

Company shall provide to the Successor in Interest, by registered mail, a copy of the Consent Order and the "Notice of Transfer" document which is incorporated by reference as Attachment B to this Order.

(2) Notice to EPA. Within 10 business days of the effective date of the transfer, the Company shall, by registered mail, submit the fully executed Notice of Transfer document to: U.S. Environmental Protection Agency, New Chemicals Branch (7405), 1200 Pennsylvania Avenue, N.W., Washington, D.C. 20460.

(3) Transfer Document. Copies of the Transfer Document must be maintained by the Successor in Interest at its principal place of business, and at all sites where the PMN substances are manufactured. Copies of the Transfer Document must also be made available for inspection pursuant to Section 11 of TSCA, must state the effective date and time of transfer, and must contain provisions which expressly transfer liability for the PMN substances under the terms of this Order from the Company to the Successor in Interest.

(e) Liability.

(1) The Company shall be liable for compliance with the requirements of this Order until the effective date and time of the transfer described above.

(2) The Successor in Interest shall be liable for compliance with the requirements of this Order effective as of the date and time of transfer.

(3) Nothing in this section shall be construed to prohibit the Agency from taking enforcement action against the Company after the effective date of the transfer for actions taken, or omissions made, during the time in which the Company manufactured, processed, used, distributed in commerce, or disposed of the PMN substances pursuant to the terms of this

Consent Order.

(f) Obligations to Submit Test Data under Consent Order. If paragraph (d) of the Testing section of this Consent Order requires the Company to submit test data to EPA at a specified production volume ("test trigger"), the aggregate volume of the PMN substances manufactured (which includes imported) by the Company up to the date of transfer shall count towards the test trigger applicable to the Successor in Interest.

VI. MODIFICATION AND REVOCATION OF CONSENT ORDER

The Company may petition EPA at any time, based upon new information on the health effects of, or human exposure to, the PMN substances, to modify or revoke substantive provisions of this Order. The exposures and risks identified by EPA during its review of the PMN substances and the information EPA determined to be necessary to evaluate those exposures and risks are described in the preamble to this Order. However, in determining whether to amend or revoke this Order, EPA will consider all relevant information available at the time the Agency makes that determination, including, where appropriate, any reassessment of the test data or other information that supports the findings in this Order, an examination of new test data or other information or analysis, and any other relevant information.

EPA will issue a modification or revocation if EPA determines that the activities proposed therein will not present an unreasonable risk of injury to health or the environment and will not result in significant or substantial human exposure or substantial environmental release in the absence of data sufficient to permit a reasoned evaluation of the health or environmental effects of the PMN substances.

In addition, the Company may petition EPA at any time to make other modifications to the language of this Order, including modifications to production volume limits and time periods for submission of reports and data which are necessary due to no fault of, or circumstances beyond the control of, the Company. EPA in its sole discretion, may issue such a modification if EPA determines that the modification is useful, appropriate, and consistent with the structure and intent of this Order as issued.

VII. EFFECT OF CONSENT ORDER

(a) Waiver. This Order is effective when signed below by both parties and received by EPA. By consenting to the entry of this Order, the Company waives its rights to file objections to this Order pursuant to section 5(e)(1)(C) of TSCA, to receive service of this Order no later than 45 days before the end of the review period pursuant to section 5(e)(1)(B) of TSCA, and to challenge the validity of this Order in any subsequent action. Consenting to the entry of this Order, and agreeing to be bound by its terms, do not constitute an admission by the Company as to, the facts or conclusions underlying the Agency's determinations in this proceeding. This waiver does not affect any other rights that the Company may have under TSCA.

(b) CBI Brackets. By signing this Order, the Company represents that it has carefully reviewed this document and hereby agrees that all information herein claimed as confidential by the Company (per section 14 of TSCA, 40 CFR Part 720 Subpart E, and 40 CFR Part 2) is correctly identified within brackets and that any information that is not bracketed is not claimed as confidential. To make this document available for public viewing, EPA will remove only the information contained within the brackets.

6 March 2015
Date

Maria J. Doa, Ph.D.
Director
Chemical Control Division
Office of Pollution Prevention and Toxics

3/13/15
Date

Name: [ ]

Title: [ ]

Company: [ ]

ATTACHMENT A

DEFINITIONS

[Note: The attached Order may not contain some of the terms defined below.]

"Chemical name" means the scientific designation of a chemical substance in accordance with the nomenclature system developed by the Chemical Abstracts Service's rules of nomenclature, or a name which will clearly identify a chemical substance for the purpose of conducting a hazard evaluation.

"Company" means the person or persons subject to this Order.

"Commercial use" means the use of a chemical substance or any mixture containing the chemical substance in a commercial enterprise providing saleable goods or a service to consumers (e.g., a commercial dry cleaning establishment or painting contractor).

"Common name" means any designation or identification such as code name, code number, trade name, brand name, or generic chemical name used to identify a chemical substance other than by its chemical name.

"Consumer" means a private individual who uses a chemical substance or any product containing the chemical substance in or around a permanent or temporary household or residence, during recreation, or for any personal use or enjoyment.

"Consumer product" means a chemical substance that is directly, or as part of a mixture, sold or made available to consumers for their use in or around a permanent or temporary household or residence, in or around a school, or in recreation.

"Container" means any bag, barrel, bottle, box, can, cylinder, drum, reaction vessel, storage tank, or the like that contains a hazardous chemical. For purposes of this section, pipes or piping systems, and engines, fuel tanks, or other operating systems in a vehicle, are not considered to be containers.

"Contract Manufacturer" means a person, outside the Company, who is authorized to manufacture and import the PMN substance under the conditions specified in Part II. of this Consent Order and in the Consent Order for Contract Manufacturer.

"Final Formulation of the PMN substances" means the formulated dispersion or solution of the PMN substances in the form in which it is sold to customers outside the Company or transferred to a different business unit within the Company. The term does not include intermediate dilutions of the PMN substances that are intended only for use within the Company for further dilution prior to sale.

"Identity" means any chemical or common name used to identify a chemical substance or a mixture containing that substance.

"Immediate use." A chemical substance is for the "immediate use" of a person if it is under the control of, and used only by, the person who transferred it from a labeled container and will only be used by that person within the work shift in which it is transferred from the labelled container.

"Industrial use." An industrial use is a use at a site at which one or more chemical substances or mixtures are manufactured (including imported) or processed.

"Initially Isolated Formulations of the PMN substances" means a common intermediate PMN formulation, as it exists when first produced and isolated after the polymer manufacturing process, that can be further processed or repackaged at the direction of the Company to result ultimately in one or more final formulations of the PMN substances.

"Manufacturing stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of manufacture, including the cleaning of equipment.

"MSDS" means material safety data sheet, the written listing of data for the chemical substance.

"NIOSH" means the National Institute for Occupational Safety and Health of the U.S. Department of Health and Human Services.

"Non-enclosed process" means any equipment system (such as an open-top reactor, storage tank, or mixing vessel) in which a chemical substance is manufactured, processed, or otherwise used where significant direct contact of the bulk chemical substance and the workplace air may occur.

"Non-industrial use" means use other than at a facility where chemical substances or mixtures are manufactured, imported, or processed.

"PMN substances" means the chemical substance (see TSCA s. 3(2)) described in the Premanufacture notices submitted by the Company relevant to this Order.

"Process stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of processing, including the cleaning of equipment.

"Scientifically invalid" means any significant departure from the EPA-approved protocol or the Good Laboratory Practice Standards at 40 CFR Part 792 without prior or subsequent Agency approval that prevents a reasoned evaluation of the health or environmental effects of the PMN substances.

"Scientifically equivocal data" means data which, although developed in apparent conformity with the Good Laboratory Practice Standards and EPA-approved protocols, are inconclusive, internally inconsistent, or otherwise insufficient to permit a reasoned evaluation of

the potential risk of injury to human health or the environment of the PMN substances.

"Sealed container" means a closed container that is physically and chemically suitable for long-term containment of the PMN substances, and from which there will be no human exposure to, nor environmental release of, the PMN substances during transport and storage.

"Use stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of industrial, commercial, or consumer use.

"Workplace" means an establishment at one geographic location containing one or more work areas.

ATTACHMENT B

NOTICE OF TRANSFER
OF
TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER

_____ _____
Company (Transferor) PMN Number

1. Transfer of Manufacture Rights. Effective on _____, the Company did sell or otherwise transfer to _____, ("Successor in Interest") the rights and liabilities associated with manufacture of the above-referenced chemical substance, which was the subject of a premanufacture notice (PMN) and is governed by a Consent Order issued by the U.S. Environmental Protection Agency (EPA) under the authority of §5(e) of the Toxic Substances Control Act (TSCA, 15 U.S.C. §2604(e)).

2. Assumption of Liability. The Successor in Interest hereby certifies that, as of the effective date of transfer, all actions or omissions governed by the applicable Consent Order limiting manufacture, processing, use, distribution in commerce and disposal of the PMN substance, shall be the responsibility of the Successor in Interest. Successor in Interest also certifies that it is incorporated, licensed, or doing business in the United States in accordance with 40 CFR 720.22(3).

3. Confidential Business Information. The Successor in Interest hereby:

___ reasserts,

___ relinquishes, or

___ modifies

all Confidential Business Information (CBI) claims made by the Company, pursuant to Section 14 of TSCA and 40 CFR part 2, for the PMN substance(s). Where "reasserts" or "relinquishes" is indicated, that designation shall be deemed to apply to all such claims. Where "modifies" is indicated, such modification shall be explained in detail in an attachment to this Notice of Transfer. Information which has been previously disclosed to the public (e.g., a chemical identity that was not claimed as CBI by the original submitter) would not subsequently be eligible for confidential treatment under this Notice of Transfer.

TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER

NOTICE OF TRANSFER
(continued)

Company (Transferor) PMN Number

Signature of Authorized Official Date

Printed Name of Authorized Official

Title of Authorized Official

Successor in Interest

Signature of Authorized Official Date

Printed Name of Authorized Official

Title of Authorized Official

Address

City, State, Zip Code

TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER

NOTICE OF TRANSFER
(continued)

_____
Successor's Technical Contact

_____
Address

_____
City, State, Zip Code

_____
Phone